K010831

JUN 13 2001

ATTACHMENT 4

510(k) SUMMARY

The 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92

Submitter's Name: Guidant Corporation
Vascular Intervention, Inc.

Submitter's Address: 26531 Ynez Road
Temecula, CA 92591

Telephone: (909) 914-2631
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Contact Person: Merritt Girgis

Date Prepared: March 15, 2001

Device Trade Name: AVIATOR™ Peripheral Dilatation Catheter

Device Common Name: Peripheral Dilatation Catheter

Device Classification Name: Peripheral Dilatation Catheter

Device Classification: Class II

Summary of Substantial Equivalence:

The design, materials, method of delivery and intended use features of the AVIATOR™ Peripheral Dilatation Catheter is substantially equivalent with regard to these features in the predicate device, the RX VIATRAC™ 14 Peripheral Dilatation Catheter (K983055).

Device Description:

Like the predicate RX VIATRAC™ 14, the AVIATOR™ Peripheral Dilatation Catheter has an integrated shaft system and a balloon bonded to the distal end. The shaft has a combination of single lumen and dual lumen tubing. One lumen is used for inflation of the balloon with contrast medium. The second lumen in the distal shaft permits the use of a guidewire to facilitate the advancement of the catheter to and through the stenosis to be dilated. The catheter shaft has a distal port (hole) approximately 29 cm from the distal tip that accesses the guidewire lumen. The guidewire lumen begins at the distal port and ends at the distal tip.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 3 2001

Mr. Merritt Girgis
Sr. Regulatory Affairs Coordinator
Guidant Corporation
Vascular Intervention Group
26531 Ynez Rd
Temecula, CA 92589-9018

Re: K010831
Trade Name: AVIATOR™ Peripheral Dilatation Catheter
Regulatory Class: II
Product Code: DQY
Regulation: 870.1250
Dated: May 11, 2001
Received: May 14, 2001

Dear Mr. Girgis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

ATTACHMENT 2

Indications for Use Statement

510(k) Number (if known) K010831

Device Name AVIATOR™ Peripheral Dilatation Catheter

Indications for Use

The AVIATOR™ Peripheral Dilatation Catheter is intended:

a) To dilate stenosis in the peripheral arteries (iliac, femoral, ilio-femoral, popliteal, infra popliteal, renal arteries) or for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

b) For post-stent dilatation of the PALMAZ™ P204 stent with the 20 mm balloon length only, implanted in vessels ranging from 4.0 mm to 7.0 mm in diameter.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010831